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(74) Agents: **HAN, Johnney, U. et al.**; Morrison & Foerster LLP,
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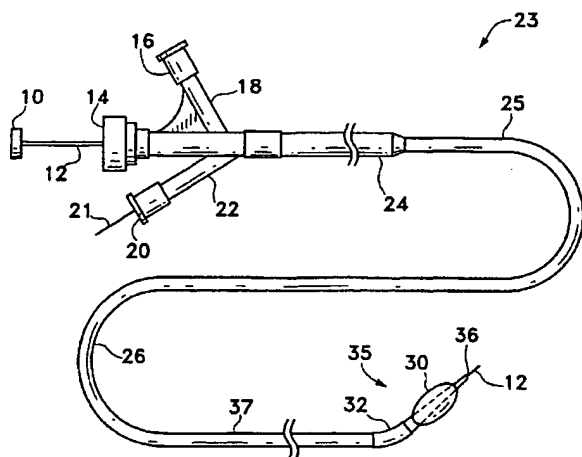
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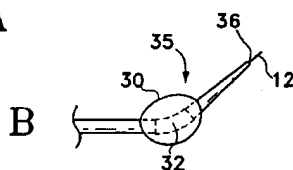
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[Continued on next page]

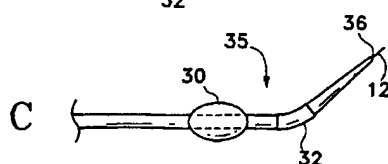
(54) Title: MANIPULATABLE DELIVERY CATHETER FOR OCCLUSIVE DEVICES



A



B



C

(57) Abstract: A delivery catheter (23) with a flexible, proximally-manipulated hinge (32) or joint region and a balloon (30) may have a shaft (25) of varying flexibility which contains several lumen. The inner, or delivery, lumen generally may be used with a guidewire (12) to access target sites within the body via the flexible, small diameter vessels, and may be also used for placement of occlusive materials, e.g., in an aneurysm. The push/pull wire lumen contains a wire (21), which when manipulated, flexes the catheter's distal tip. Moreover, the delivery catheter can be twisted in a helical or corkscrew-like manner for traversing certain vasculature, by winding the push/pull wire within the catheter and fixedly attaching it. The catheter may further include an entry in the catheter wall to allow for the insertion of a guidewire; to facilitate the rapid exchange of catheter devices.

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INTERNATIONAL SEARCH REPORT

International Application No

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A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M25/01 A61M25/10 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 6 071 279 A (FLEISCHMAN SIDNEY D ET AL) 6 June 2000 (2000-06-06) column 24, line 46 -column 26, line 67; figures 45-49C,55	1,4,5,18 19,32, 36,41
X A	DE 199 49 590 A (CARDIOTHORACIC SYS INC) 21 June 2000 (2000-06-21) the whole document	19,21, 22,26,27 32,36,41
X A	US 5 391 146 A (THAT DAI T ET AL) 21 February 1995 (1995-02-21) abstract; figure 3 column 3, line 10 -column 5, line 5; figures 1,2	19,26,36 1,18,32, 41
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Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
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- *&* document member of the same patent family

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 01 03766 A (BARD INC C R) 18 January 2001 (2001-01-18) page 5, line 8 -page 6, line 24; figures 2,3,8-10 ----	19,21,22
X	US 4 798 598 A (JEANMONOD MAURICE ET AL) 17 January 1989 (1989-01-17) abstract; figures 1-5 ----	19,27
A	----- US 6 036 717 A (PHELPS DAVID Y ET AL) 14 March 2000 (2000-03-14) abstract; figures 1-3 column 5, line 14-42 ----	1,6,7, 18,32, 36,41
A	----- US 6 036 717 A (PHELPS DAVID Y ET AL) 14 March 2000 (2000-03-14) abstract; figures 1-3 column 5, line 14-42 ----	1,11,18, 19,32, 36,41
A	----- EP 0 900 575 A (CORDIS WEBSTER INC) 10 March 1999 (1999-03-10) page 4, column 6, line 12 -page 5, column 8, line 37; figures 28-3,9-11 ----	1-42
A	----- US 5 478 330 A (GLYNN BRIAN A ET AL) 26 December 1995 (1995-12-26) column 5, line 46 -column 6, line 15; figures 6-8C column 7, line 28 -column 9, line 32; figures 11-18 column 12, line 7 -column 13, line 31; figures 1,22,23 ----	1-42
A	----- US 5 480 382 A (HAMMERSLAG GARY R ET AL) 2 January 1996 (1996-01-02) abstract column 9, line 3-22; figures 4,5 column 13, line 62 -column 14, line 8; figures 8,10 column 15, line 36 -column 17, line 45; figures 12,13 ----	1-42
A	----- US 5 368 592 A (STERN ROGER A ET AL) 29 November 1994 (1994-11-29) abstract; figure ALL -----	1-42

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 01/25780

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/SA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-18

Catheter section comprising a balloon region, an inflatable member, a flexible joint region and a wire to flex the joint region, and a catheter comprising inner tubing member, guidewire, inflation member, push/pull member and wire, and a flexible joint region.

2. Claims: 19-31

Catheter section comprising flexible joint region, wire to move distal catheter section about the joint, where a portion of wire distal end is angularly disposed in relation to section axis.

3. Claims: 32-35

Catheter section comprising a balloon region, an inflatable member, a flexible joint region, a tubing member with variable wall thickness and a wire to move distal end about the joint where the wire is disposed in the tubing member.

4. Claims: 36-40

Catheter section comprising a flexible joint region, a wire to move the catheter distal end about the joint, where a portion of the wire distal end is angularly disposed in relation to the section axis, and a guidewire entry section.

5. Claims: 41-42

A catheter section comprising a flexible joint, a wire to move catheter distal end about the joint and to move catheter distal end about the section axis.

INTERNATIONAL SEARCH REPORT
Information on patent family members

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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INTERNATIONAL SEARCH REPORT

information on patent family members

International Application No

PCT/US 01/25780

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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94705 (US). **LEVINE, Marc-Alan** [US/US]; 2030 46th
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(21) International Application Number: PCT/US01/25780

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(63) Related by continuation (CON) or continuation-in-part
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patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,
IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF,
CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD,
TG).

(71) Applicant (*for all designated States except US*):
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(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **HEBERT, Stephen**
[US/US]; 2801 College Avenue, Apt. 3, Berkeley, CA

*For two-letter codes and other abbreviations, refer to the "Guidance
Notes on Codes and Abbreviations" appearing at the beginning
of each regular issue of the PCT Gazette.*

WO 02/15972 A2

(54) Title: MANIPULATABLE DELIVERY CATHETER FOR OCCLUSIVE DEVICES

(57) Abstract: This is in the general field of surgical instruments and is specifically a delivery catheter with a flexible, proximally-manipulated hinge or joint region. The inventive catheter may have a balloon region. The catheter may have a shaft of varying flexibility which contains several lumen. The inner, or delivery, lumen generally may be used with a guidewire to access target sites within the body via the flexible, small diameter vessels of the body. The delivery lumen may be also used for placement of occlusive materials, e.g., in an aneurysm. Inflation of the micro-balloon, located near the distal tip of the catheter, is effected using the inflation lumen. The push/pull wire lumen contains a wire, which when manipulated, flexes the catheter's distal tip. The push/pull wire tubing may have a variable thickness to aid in adjusting the degree of flexibility. Moreover, the delivery catheter may be capable of twisting in a helical or corkscrew-like manner for traversing certain vasculature. This may be accomplished by winding the push/pull wire within the catheter and fixedly attaching it. The catheter may further include an entry in the catheter wall to allow for the insertion of a guidewire; this may facilitate the rapid exchange of catheter devices as desired by the user.

MANIPULATABLE DELIVERY CATHETER FOR OCCLUSIVE DEVICES

CROSS-REFERENCE TO RELATED APPLICATIONS

5 This application claims the benefit of priority to U.S. Patent Application Serial
Number 09/643,085 entitled "MANIPULATABLE DELIVERY CATHETER FOR
OCCLUSIVE DEVICES" filed August 21, 2000, and U.S. Patent Application Serial
Number 09/703,468 entitled "MANIPULATABLE DELIVERY CATHETER FOR
OCCLUSIVE DEVICES (II)" filed October 31, 2000, each of which are co-pending and are
10 incorporated by reference in their entirety.

FIELD OF THE INVENTION

 This invention is in the general field of surgical instruments and is specifically a
catheter having a flexible, proximally-manipulated hinge region. The inventive catheter
15 may include a balloon. The catheter may have a shaft of varying flexibility which contains
several lumen. The inner, or delivery, lumen generally may be used with a guide wire to
access target sites within the body through the flexible, small diameter vessels of the body.
The delivery lumen may be also used for placement of occlusive materials, e.g., in an
aneurysm. Inflation of the optional micro-balloon, located near the distal tip of the
20 catheter, is effected using the inflation lumen. The push/pull wire tubing contains a wire,
which when manipulated, flexes the catheter's distal tip.

BACKGROUND OF THE INVENTION

 Endovascular therapy has been used to treat different conditions, such treatments
25 including control of internal bleeding, occlusion of blood supply to tumors, and occlusion
of aneurysm. Often the target site of the malady is difficult to reach. Because of their
ability to access remote regions of the human body and deliver diagnostic or therapeutic
agents, catheters are increasingly becoming components of endovascular therapies.
Vascular catheters may be introduced into large arteries, such as those in the groin or in the
30 neck, and then pass through narrowing regions of the arterial system until the catheter's
distal tip reaches the selected delivery site. To be properly utilized, catheters are often

stiffer at their proximal end to allow the pushing and manipulation of the catheter as it progresses through the body but sufficiently flexible at the distal end to allow passage of the catheter tip through the body's blood vessels without causing significant trauma to the vessel or surrounding tissue.

5 Microcatheters, such as those shown in U.S. Pat. Nos. 4,884,579 and 4,739, 768, each to Engleson, allow navigation through the body's tortuous vasculature to access such remote sites as the liver and the arteries of the brain. Although other methods of causing a catheter to proceed through the human vasculature exist (e.g., flow directed catheters), a guidewire-aided catheter is considered to be both quicker and more accurate than other
10 procedures. Catheters with deflectable or variable stiffness distal ends (which increase the flexibility of the catheter's distal end) have been disclosed in U.S. Pat. No. 6,083,222, to Klein et al; U.S. Pat. No. 4,983,169, to Furukawa; U.S. Pat. No. 5,499,973, Saab; and U.S. Pat. No. 5,911,715, to Berg et al.

 The addition of a fluid-expandable balloon on the distal end of the catheter and a
15 coupler on the proximal end allows various percutaneous medical treatments such as pressure monitoring, cardiac output and flow monitoring, angioplasty, artificial vaso-occlusion, and cardiac support. Balloon catheters generally include a lumen that extends from the proximal end and provides fluid to the balloon for inflation. Examples of balloon catheters are disclosed in U.S. Pat. No. 4,813,934 to Engleson et al and U.S. Pat. No. 5,
20 437,632 to Engelson et al. A balloon catheter with an adjustable shaft is shown in U.S. Pat. No. 5,968,012, to Ren et al.

 For certain vascular malformations and aneurysms, it may be desirable to create an endovascular occlusion at the treatment site. A catheter is typically used to place a vaso-occlusive device or agent within the vasculature of the body either to block the flow of
25 blood through a vessel by forming an embolus or to form such an embolus within an aneurysm stemming from the vessel. Formation of an embolus may also involve the injection of a fluid embolic agent such as microfibrillar collagen, Silastic beads, or polymeric resins such as cyanoacrylate. Ideally, the embolizing agent adapts itself to the irregular shape of the internal walls of the malformation or aneurysm. Inadvertent
30 embolism due to an inability to contain the fluid agent within the aneurysm is one risk which may occur when using fluid embolic agents.

Mechanical vaso-occlusive devices may also be used for embolus formation. A commonly used vaso-occlusive device is a wire coil or braid which may be introduced through a delivery catheter in a stretched linear form and which assumes an irregular shape upon discharge of the device from the end of the catheter to fill an open space such as an aneurysm. U.S. Pat. No. 4,994,069, to Ritchart et al, discloses a flexible, preferably coiled, wire for use in a small vessel vaso-occlusion.

Some embolic coils are subject to the same placement risks as that of fluid embolic agents in that it is difficult to contain the occlusive coil within the open space of the aneurysm. A need exists for a delivery system which accurately places the occluding coil or fluid and ensures that the occluding coil or fluid does not migrate from the open space within the aneurysm. The delivery catheter must have a small diameter, have a highly flexible construction which permits movement along a small-diameter, tortuous vessel path, have a flexible method of placement to ensure accuracy, and must have a method to prevent coil or embolizing agent leakage.

15

SUMMARY OF THE INVENTION

This invention is a catheter or catheter section. Although it desirably has a balloon region located from distal of an inflatable member to proximal of that inflatable member, where the inflatable member is within the balloon region, it need not have a balloon region or an inflatable member. The inventive catheter has a flexible joint region located generally in the distal area of the catheter, often within that balloon region. The catheter includes a wire configured to flex the flexible joint region. Where the catheter includes an inflatable member, the flexible joint may variously be distal of the inflatable member, within the inflatable member, or proximal of the inflatable member. The flexible joint region preferably has a flexibility of up to about 90°. The flexible joint region, because the catheter wire may be too rigid, may also be manipulatable in a circular direction relative to the axis of the catheter.

The wire may be slidably held, e.g., within a separate tubing. This tubing may potentially be used to aid in adjusting the flexibility of the joint region. This may be accomplished by several different variations. One variation utilizes a wire tubing having collinear consecutive sections of decreasing wall thickness. Alternatively, the wire tubing

30

may be tapered according to the desired degree of joint flexibility. The tubing itself may be a braided tubing which may be of varying flexibility.

The flexible joint itself may be, for instance, a coil member, perhaps having a section with a pitch which is larger than adjacent coil pitches. The flexible joint may
5 instead be a braid, perhaps with a section with a pic which is larger than the pic of one or more adjacent sections. The flexible joint may also be made up of a polymer tubing with a section which is softer than adjacent tubing polymers or a region having a wall thickness that is thinner than adjacent wall thickness.

In taking advantage of the flexibility and capabilities of the present invention, a
10 variation capable of twisting in a helical or corkscrew-like manner may be accomplished with or without an inflatable member or balloon region. This variation is particularly useful in traversing tortuous vasculature and in making difficult approaches to aneurysms. This alternative variation utilizes a wire which may be wound about the guidewire or inner tubing and fixedly attached. It is thus possible to wind the wire any number of times or just
15 a few degrees off the wire axis depending upon the vasculature being traversed and the degree of flexibility or twisting desired. Moreover, different variations may be developed capable of twisting in a left or right handed orientation.

The present invention may also incorporate various rapid exchange variations.

The inflatable member or balloon may be of a material selected from the group
20 consisting of elastomers such as silicone rubber, latex rubber, natural rubber, butadiene-based co-polymer, EPDM, and polyvinyl chloride or thermoplastic polymers such as polyethylene, polypropylene, and nylon.

BRIEF DESCRIPTION OF THE DRAWINGS

25 Figures 1A, 1B, and 1C are external views of several variations of the inventive catheter device.

Figure 2A depicts a cross sectional view of a proximally placed hinge region in a variation of the distal region of the inventive catheter.

Figure 2B depicts a cross sectional view of a mid-balloon hinge region placement
30 for a variation of the distal region of the inventive catheter.

Figure 2C depicts a cross sectional view of a distally placed hinge region in a variation of the distal region of the inventive catheter.

Figure 2D depicts a cross sectional view of an additional mid-balloon hinge region placement for one variation of the distal region of the inventive catheter.

5 Figure 3A depicts a cross-sectional view of an alternate hinge region construction for the distal region of the inventive catheter. The hinge region of Figure 3A is composed of a section of material which is surrounded by regions of greater stiffness.

10 Figure 3B depicts a cross-sectional view of an alternate hinge region construction for the distal region of the inventive catheter. The hinge region of Figure 3B is composed of a coil of varying pitch.

Figure 3C depicts a cross-sectional view of an alternate hinge construction for the distal region of the inventive catheter. The hinge of Figure 3C is composed of a region of thinned tubing wall surrounded by regions of thickened tubing wall.

15 Figure 3D depicts a cross-sectional view of an alternate hinge region construction for the distal region of the inventive catheter. The hinge region of Figure 3B is composed of a braided region which is flanked by regions of higher braid density.

Figures 4A-4H are cross-sectional views of catheter shafts displaying the various relative positions of the push/pull wire lumen, inflation lumen, and delivery lumen.

20 Figure 5 depicts the positions of the radio-opaque markers positioned within the distal end of the catheter tip.

Figure 6A depicts the relative position of the distal end of the catheter tip when not flexed.

Figure 6B depicts the relative position of the distal end of the catheter when flexed by pulling the push/pull motion wire.

25 Figure 6C depicts the relative position of the distal end of the catheter when flexed by pushing the push/pull motion wire.

Figure 7A depicts a variation having a push/pull wire tubing with consecutively smaller cross-sections.

Figure 7B depicts an alternative variation having a tapering push/pull wire tubing.

Figure 7C depicts a cross-sectional view of the sectioned push/pull wire tubing from Figure 7A.

Figure 7D depicts a cross-sectional view of the tapered push/pull wire tubing from Figure 7B.

5 Figure 8A depicts a variation where the push/pull wire may be partially wound about the guidewire tubing.

Figure 8B depicts a cross-section of Figure 8A where the push/pull wire is wound in a right-handed orientation.

10 Figure 8C depicts a cross-section of Figure 8A with an alternative variation where the push/pull wire is wound in a left-handed orientation.

Figure 9 depicts a variation having a catheter tip which may be rotated by a twisting push/pull wire.

Figures 10A, 10B, and 10C are external views of several variations of the inventive catheter device incorporating a rapid exchange variation.

15 Figures 11A, 11B, 11C, and 11D depict the steps of using the inventive catheter by respectively inserting the distal end of the inventive catheter into a blood vessel, placing a vaso-occlusive device within an aneurysm, and removing of the catheter.

DETAILED DESCRIPTION OF THE INVENTION

20 This invention involves a multi-lumen, catheter having a manipulatable distal tip and is for the delivery of vaso-occlusive materials or implants. The inventive catheter may include one or more distally placed balloon members. The device is shown in detail in the Figures wherein like numerals indicate like elements. The catheter preferably includes a shapeable, flexible distal section. The flexible section, or "hinge region", preferably is
25 manipulated from outside the body during the process of delivering the vaso-occlusive device or material. The terms "hinge region", "hinge", or "flexible joint" may be used interchangeably for our applications.

Figure 1A shows a catheter assembly 23 made according to one variation of the invention. This variation of the catheter assembly 23 includes a catheter shaft 25

comprised of a flexible, thin walled body or tube 26 having an inner lumen which extends between proximal and distal catheter ends 24, 37, respectively. The tube 26 is preferably a generally nondistensible polymer having the appropriate mechanical properties for this application, and preferably polyethylene (e.g., HDPE, LDPE, LLDPE, MDPE, etc.),
5 polyesters (such as Nylon), polypropylene, polyimide, polyvinyl chloride, ethylvinylacetate, polyethylene terephthalate, polyurethane (e.g. Texin such as that made by Bayer Corporation), PEBAX, fluoropolymers, mixtures of the aforementioned polymers, and their block or random co-polymers.

This variation of the inventive catheter assembly generally has several overall
10 functions: a.) access through the vasculature to the brain (or other vascular site) often, but not necessarily, using a guide wire; b.) inflation of the inflatable member or balloon to close or to restrict an artery or the mouth of an aneurysm prior to or during placement of a vaso-occlusive device, thereby requiring a fluid pathway for inflation of the inflatable member; c.) flexion of a "hinge region" in the neighborhood of the distal end of the
15 catheter by a wire extending proximally through the catheter; and d.) introduction of a vaso-occlusive device or material for eventual placement in the vasculature, thereby requiring a pathway or storage region for the vaso-occlusive device. These functions may be achieved by features found at the proximal and distal regions of the catheter.

The proximal catheter end 24 may be provided with a fitting 18 (e.g., a "LuerLok")
20 through which fluid may be supplied to the catheter's inflation lumen through a side port 16. The proximal end of the catheter is provided with a second port 20 and a fitting 22 through which a push/pull wire may be used to manipulate the hinge region 32 in the distal catheter tip. The proximal end fitting 18 includes an axially extending port 14 which communicates with the catheter's delivery/guide wire lumen. The optional guide wire 12
25 may have any suitable construction for guiding the flexible catheter to its intended site within the body. The proximal end of the guide-wire 12 may be equipped with a handle 10 for applying torque to the guide wire 12 during catheter operation. The guide-wire may have a variable stiffness or stepped diameter along its length which typically, e.g., a larger-diameter, stiffer proximal region and one or more smaller-diameter, more flexible distal
30 regions.

The distal portion 35 of the catheter is made of an inflatable member 30, typically a balloon, a hinge region 32, and an opening or aperture 36 for delivery of the vaso-occlusive

device or material. This opening 36 may also be used for delivery of drugs and the vaso-occlusive device to the selected vascular site. The distal end region 35 of the catheter 25 is provided with an inflatable balloon 30 which, when inflated, aids in the placement of vaso-occlusive materials or devices by blocking the entrance to the aneurysm or the artery adjacent to the aneurysm.

The balloon wall section (discussed in greater detail below) is preferably formed from a thin sleeve of polymeric material and attached at its opposite sleeve ends to a relatively more rigid tube section. Figures 1A, 1B, and 1C display various configurations of the distal catheter tip 35 positioning based on the placement of the flexible hinge region. Figures 1A, 1B, and 1C respectively show variations of the inventive catheter 23 in which the hinge region 32 is placed proximal to (Figure 1A), within (Figure 1B), and distal to (Figure 1C) the inflatable member region 30. Flexion of the hinge region is achieved through remote manipulation of the push/pull wire 21.

Figures 2A through 2D illustrate variations of the distal end region 35 and hinge region 32 of the catheter illustrated in Figure 1A, 1B, and 1C.

The catheter tube 40 of Figure 2A has an inflatable member 44, preferably a balloon, which is formed by an inflatable sleeve secured at its ends 41, 43 to the catheter tube wall 40. The inflatable member or balloon 44 may be of a shape, thickness, and material as is typical of balloons used in neurovascular balloon catheters. Preferably, though, the inflatable member or balloon 44 is formed of a thin polymeric material, and preferably an elastomeric, stretchable material such as silicone rubber, latex rubber, polyvinyl chloride, complex co-polymers such as styrene-ethylene butylene-styrene copolymers such as C-FLEX, or alternatively, a non-stretchable film material such as polyethylene, polypropylene, or polyamides such as Nylon. Attachment of the sleeve ends to the catheter tube may be by gluing, heat shrinkage, mechanical fastener, or other suitable method. The inflation lumen 42 allows communication between the inflation fluid source and the balloon 44 through at least one opening 50 formed in the catheter tube 40. Inflation and deflation of the balloon are effected by the passage of radio-opaque fluid, saline, or other fluid. The push/pull wire tubing 60 extends throughout the catheter tube 40 and protects the passage of the push/pull wire 62 which is connected to the inner wall of the catheter tube 40. To assist in preventing collapse of the tube 60 enclosing the push/pull wire 62 and to prevent kinking or bulging during actuation, the push/pull wire tubing 60

may have additional structure preferably provided by a layer of higher stiffness polymer (e.g., a polyimide), a support coil, or a support braid.

5 Axial manipulation of the push/pull wire 62 via the proximal wire port (20 in Figure 1A) allows flexion of the distal end 35 of the catheter (25 in Figure 1A). The guide wire 57 extends through the delivery lumen 55 which lies interior to the catheter tube 40. The push/pull wire 62 extends through the push/pull wire tubing 60 and may be bonded to the radio-opaque band 67 which surrounds the catheter's distal end 65. Radio-opaque bands may be made of any number of conventional radio-opaque materials, e.g., platinum. The hinge region 58 at which the distal catheter tip 65 flexes due to proximal manipulation of the push/pull wire 62 may be located proximal to, within, or distal to the balloon, as displayed respectively in Figures 2A, 2B, and 2C.

As shown in Figure 2A, when the hinge region 58 is placed proximally of the balloon 44, the push pull wire tubing 60 extends to a region which is proximal of the distal end of the balloon 44 to allow flexion of the region of the catheter's distal end 65 which includes the entire balloon 44. If the hinge region 58 is placed interior to the balloon, as in Figure 2B, flexion of the catheter's distal end 65 occurs such that the point of flexion is within the balloon (also displayed in Figure 1B). Figure 2C shows the placement of hinge 58 distal to the balloon; flexion during distal-hinge placement occurs such that the manipulatable region of the catheter's distal end 65 does not include any portion of the balloon 44.

Figure 2D shows placement of the hinge region 58 interior to the balloon 44. The balloon 44 extends between the guidewire/delivery tube 56 and the outer catheter tube 40 enclosing the annular inflation lumen 42. The push/pull wire 62 is attached to the distal end 65 of the guidewire/delivery tube 56.

25 In each of the variations shown in Figs. 2A, 2B, 2C, and 2D, the push/pull wire 62 is distally attached to a radio-opaque band 67. Although this is a preferred variation, other attachment sites for attachment of the push/pull wire 62 distal to the hinge region 58 will be apparent.

30 The hinge region may be made up of any material or structural configuration which allows flexion based on remote manipulation by movement of the push/pull wire 62. Several variations of preferred configuration are shown in Figures 2D, 3A, 3B, and 3C.

In Figure 2D, extension of the delivery tube 56 beyond the end of the inflation lumen 42 allows remote manipulation of the catheter's distal end 65 if the push/pull wire 62 is attached to a marker or platinum band 67 which is located distal to the end of the inflation lumen. In this configuration, remote manipulation of the push/pull wire allows flexion to occur between the end of the inflation lumen 42 and the marker 67 to which the push/pull wire 62 is attached. The delivery tube 56 may be made of any of the materials listed above with respect to tube 26 in Figure 1.

Figure 3A displays a cross section of the catheter 70 wall. The hinge section of Figure 3A is made from contiguous regions of tubing where one section of the catheter wall 77 is made from a material with a stiffness which is less than the stiffness of the material of the flanking sections of catheter wall 75, 79. These regions of tubing are preferably made through extrusion, by doping, or heat treating a region of the tubing.

Figure 3B displays a hinge region 88 which utilizes a coil 90 of varying pitch imbedded in the catheter wall. Because the variation in pitch of the coil 90 produces regions of varying flexibility, the lower pitch region 88 is more flexible than the region of higher pitch 89. The higher pitch region 89 is stiffer during manipulation of the push/pull wire 86.

As shown in Figure 3C, if a thinned region of catheter wall 105 is flanked by regions of greater wall cross-sectional area 100, 108, the section 108 of the catheter wall which is distal to the thinned section 105 will act as a hinge when the distal end of the catheter is manipulated using the push/pull wire 96. The variations in wall cross sectional area may preferably be created during an extrusion process.

Figure 3D displays a hinge which utilizes a braided ribbon 94 with varying braid pitch, that is embedded between outer 101 and inner 103 layers of the catheter wall. The variation in pitch of the braided ribbon 105 produces regions of varying flexibility. If a region of lower braid pitch 92 is flanked by regions of higher braid pitch 90, the region of greater pitch 89 is stiffer during manipulation of the distal catheter tip. The braid 94 is preferably made from a number of metallic ribbons or wires which are members of a class of alloys known as super-elastic alloys, but may also be made from other appropriate materials such as stainless steel or polymers such as liquid crystal polymers (LCP's). Preferred super-elastic alloys include the class of titanium/nickel materials known as

nitinol. Additional treatment to the braid prior to assembly, such as heat-treatment, may be required or desired to prevent braid unraveling, changes in diameter, or spacing during handling. The braids which may be utilized in this invention are preferably made using commercially available tubular braiders. The term "braid" is meant to include tubular
5 constructions in which the ribbons making up the construction are woven radially in and in-and-out fashion as they cross to form a tubular member defining a single lumen. The braid is preferably made from a suitable number of ribbons or wires.

Some of the various configurations of the catheter's lumina (inflation, push/pull, and delivery) are displayed in Figures 4A through 4H. In Figure 4A, the inflation lumen
10 122 and push/pull wire lumen 124 are formed interior to the catheter wall 120, while the interior catheter wall forms the guide wire lumen 128. In Figure 4B, the catheter wall 120 forms the guide wire lumen 128 which contains the inflation lumen 122 and push/pull wire lumen 124. The inflation lumen 122 is formed interior to the catheter wall 120 of Figure 4C, while the push/pull wire lumen 124 lies within the larger coil lumen 128 (which is
15 formed by the catheter wall 120). Figure 4D is a variation of Figure 4C in which the push/pull wire lumen 124 lies interior to the catheter wall 128 while the inflation lumen 122 lies within the larger coil lumen 128. In Figure 4E, the interior catheter wall 120 forms the inflation lumen 122, and the push/pull wire lumen 124 and the guide wire lumen 128 are found within the inflation lumen 122. The inflation lumen 122 surrounds the guide
20 wire lumen 128 and lies within the region formed interior catheter wall 120 in Figure 4F, while the push/pull wire lumen 124 lies within the catheter wall 120. In Figure 4G, one shared lumen 123 serves as the push/pull and inflation lumen; the shared push/pull and inflation lumen 123 along with the guide wire lumen 128 lie within the catheter wall 120. Another alternate variation of the lumina positioning, shown in Figure 4H, has the
25 push/pull wire lumen 124 lying interior to the inflation lumen 122 which is contained within the catheter wall 120, while a separate lumina for the guide wire 128 also is contained within the catheter wall.

The tube constructions, hinge region construction, and other tubing forming the various lumina discussed herein may be created through extrusion, sequential production
30 (in which the parts are manufactured separately and later assembled together), or some other method.

As displayed in Figure 5, another variation of the present invention may involve the addition of radio-opaque markers 190. The lengthened distal section 200 may be provided with a number of spaced radio-opaque markers 190, 191, 192, and 193. Balloon markers 195, 196 may be provided to indicate the position of the balloon during the vascular
5 procedure. The markers may be spaced, for instance, such that the inter-marker distance corresponds to the length of the coil to be delivered. Markers 195, 196 may be spaced apart by a known or predetermined distance, e.g., 3 cm, both proximally and distally of the balloon member. Also, the various markers, particularly those located adjacent the balloon member, may be disposed outside the balloon member, as depicted, or optionally inside.

10 Figures 6A, 6B, and 6C show the operation of the inventive flexible distal catheter tip.

In Figure 6A, the remotely-manipulatable distal end 136 extends beyond the hinge 135 and allows greater access to the delivery site of the vaso-occlusive member 137 during surgical procedures. Manipulation of the push/pull wire 143 allows flexion of the catheter
15 distal tip 136.

If the push/pull wire 143 is pushed or axially manipulated, as shown in Figure 6B, the distal tip 145 is flexed upward through an angle determined by the pressure applied to the push/pull wire. Generally, the deflection angle of the catheter 140 as the push/pull wire 143 is pushed may approach up to about 90° in one direction.

20 If the push/pull wire 143 is pulled as in Figure 6C, rotation from the un-manipulated position through an angle up to about 90° opposite the direction shown in Fig. 6B is initiated; again, this angle is in a direction which is opposite to that of the pull-manipulation but generally in the same plane. The push/pull wire 143 extends through out the push/pull wire lumen 141 and may be bonded to the radio-opaque band 142 found at the distal end
25 145 of the catheter 140 tip.

Figure 7A depicts an alternative variation 210 which is similar to that shown in Fig. 2D. The tubing 56 itself may be a braided tubing which may be of varying flexibility. However, variation 210 depicts a push/pull wire tubing 212 having a stepped distal end 213. Stepped push/pull wire tubing 212 may be comprised of similar materials and
30 structures as push/pull wire tubing 60 but having a series of successively decreasing cross-sectional areas on stepped distal end 213. The number of successively decreasing cross-

sections and the associated lengths of each decreased section may vary depending upon the degree of flexibility necessary or desired within catheter distal end 65. Moreover, variation 210 depicts stepped distal end 213 extending into inflatable member 44; however, the relative positioning of stepped push/pull wire tubing 212 to inflatable member 44 may be altered again depending on the desired flexibility of catheter 40. Push/pull tubing 212 may itself be a braided tubing which may be of varying flexibility. Also, the figure depicts push/pull wire tubing 212 as a separate tube, but it may also be in any of the variational cross-sections discussed herein having the push/pull wire tubing 212 disposed, e.g., within the tubing and any braiding or coils, or disposed exteriorly of any braiding or coils.

10 Figure 7C depicts the cross-sectional view of the stepped push/pull wire tubing 212 from Figure 7A. Tubing 212 may be attached or held to tubing 56 by any of the various methods discussed herein, e.g., shrink-wrap. The figure depicts tubing 212 with three sections for illustrative purposes and tubing 212 may comprise any number of sections with variable thickness depending upon the degree of flexibility necessary or desired.

15 Figure 7B depicts an additional alternative variation 214 which is similar to variation 210. However, variation 214 depicts push/pull wire tubing 216 having a tapering distal end 217. Here, the degree of tapering may be varied depending upon the degree of flexibility necessary or desired, as above.

20 Figure 7D depicts the cross-sectional view of the tapered push/pull tubing 216 from Figure 7B. Tubing 216 may also be attached or held to tubing 56 by any of the various methods discussed herein, e.g., shrink-wrap. Tubing 216 may be made to have any degree of tapering again depending upon the degree of flexibility necessary or desired.

25 Figure 8A depicts another variation 218 which enables a user to not only manipulate catheter distal end 65 within generally one plane, but also to manipulate or to twist catheter distal end 65, e.g., in a helical or corkscrew-like manner. As illustrated, push/pull wire 62 emerges from push/pull wire tubing 60 and may be rotated about guidewire/delivery tube 56 for attachment to an attachment point, e.g., radio-opaque band 67 as shown, at some point not on the axis with the tubing 60. Instead it may be attached preferably on an opposite side from where push/pull wire 62 emerges. The attachment point is preferably located distally from push/pull wire tubing 60, but may vary depending upon the degree of torque desired. Also, attachment of push/pull wire 62 along radio-

30

opaque band 67 may also vary depending upon the desired range of torquing or twisting of catheter distal end 65. For example, push/pull wire 62 may be placed along, e.g., radio-opaque band 67, in any location ranging from about 0° where little or no twisting occurs and up to about 180° where full rotation of catheter distal end 65 occurs about a longitudinal axis defined by catheter tube 40 and guidewire/delivery tube 56. At about 0°, push/pull wire 62 is attached to radio-opaque band 67 at a point in a position to where wire 62 emerges from tubing 60. At about 180°, as depicted in Fig. 8A, push/pull wire 62 is attached to radio-opaque band 67 at a point on an opposite side of guidewire/delivery tube 56 from where wire 62 emerges.

10 In variation 218, push/pull wire tubing 60 may be held relative to guidewire/delivery tube 56 by any conventional shrink-wrap material 220 or by any number of fastening methods discussed herein. Moreover, any number of cross-sectional arrangements described herein for guidewire/delivery tube 56 and push/pull wire tubing 60 may be utilized as well. Also, the arrangement of variation 218 for wire 62 may be utilized with or without inflatable balloon member 44 and is shown in Figure 9 without balloon member 44.

Although Figure 8A depicts push/pull wire 62 wrapped half-way around guidewire/delivery tube 56, push/pull wire 62 may be wrapped any number of times around tube 56 before being attached at a desired location on radio-opaque band 67.

20 Figure 8B shows section A-A from Figure 8A depicting push/pull wire 62 wrapped in a right-handed orientation about guidewire/delivery tube 56. Wire 62 may alternatively be wrapped in a left-handed orientation about guidewire/delivery tube 56, as shown in Figure 8C, which depicts the same cross-section of Figure 8B.

In wrapping push/pull wire 62 about tube 56, manipulation of catheter distal end 65 forces wire 62 to not only undergo tensile and compressive forces along its longitudinal axis, but also torquing forces about its axis. Figure 9 depicts variation 221 without a balloon member. Alternatively, the inventive catheter design also allows twisting of the catheter tip without having to attach push/pull wire 62 along band 67 at variable positions. This may be accomplished by utilizing open area 222, the area without push/pull wire tubing 60, and the stiffness of wire 62. Wire 62 may be torqued or twisted about its own axis at its proximal end by a user to bring about a rotation of the distal end of wire 62 and,

in turn, catheter distal end 65. The degree of torquing or twisting of catheter distal end 65 may be controlled not only by the choice of catheter tubing materials, as discussed herein, but also by the length of open area 222 as well as by the choice of material and desired stiffness of wire 62. This variation may allow a catheter having a combined ability to not only be pushed and pulled in a single plane, but to also be twisted in a helical or corkscrew-like manner, if desired. Although Figure 9 depicts this variation without a balloon member, it may be used with one as described in the other variations herein. Any number of materials having sufficient strength and elasticity may be used for wire 62. Some materials which may be used include stainless steels, titanium, superelastic alloys (e.g., nitinol), or any of their combinations and alloys.

As depicted in the Figures, particularly Figures 7A-7B and 8A-8C, radio-opaque bands 67 may optionally be used in conjunction with the different variations as marking known or predetermined distances between the bands 67, as discussed above.

Figure 10A depicts variation 230 of the present invention which may incorporate rapid exchange catheter apparatus and methods. A typical rapid exchange catheter is described in detail in U.S. Patent No. 4,748,982 entitled "Reinforced Balloon Dilatation Catheter with Slitted Exchange Sleeve and Method" by Horzewski *et al.*, which is herein incorporated by reference in its entirety. In this variation 230, the apparatus and methods of the present invention, as described herein, may be used with guidewire 12. Rather than having guidewire 12 inserted from the proximal end of the catheter, guidewire 12 may instead be inserted through entry 232, which may be located along catheter 25 at a predetermined location proximal of distal end 35. This variation 230 may facilitate rapid exchanges of the inventive catheter assembly from a body lumen with other catheters, as desired by the operator.

Figures 10B and 10C depict entry 232 and insertable guidewire 12 used in conjunction with the manipulatable balloon catheter.

A remotely flexible distal tip is particularly useful when treating an aneurysm by placement of a vaso-occlusive device or material in the aneurysm. Figures 11A-11D depict such a placement.

Figure 11A displays an inventive catheter 156 that has its distal end positioned outside the mouth of an aneurysm 149 to deliver a vaso-occlusive coil. The device is positioned using a guidewire 159.

Introduction of the catheter's distal end 165 into the aneurysm neck 147, shown in
5 Figure 11B, displays the advantages of the inventive remotely manipulatable catheter. Flexion of the catheter's distal tip using the push/pull wire allows for greater maneuverability when accessing the aneurysm neck and aneurysm sac. The push/pull wire system allows the distal end to be positioned as desired during the procedure, instead of
10 before the procedure begins. Once the distal tip 165 has been properly positioned in the aneurysm neck 147, inflation of the balloon 157 is then commenced to occlude the aneurysm neck 147, as shown in Figure 11C. Full occlusion of the aneurysm neck is desirable to ensure that the coils 175 do not escape into the vessel when the coils are discharged into the aneurysm sac 149. Once the coil or coils 175 have been completely
15 discharged 180 into the aneurysm sac 149, deflation of the balloon 157 allows retraction of the catheter's distal end 165 from the aneurysm (shown in Figure 11D).

The applications of the inventive catheter discussed above are not limited to the treatment of aneurysms, but may include any number of vascular maladies. Modification of the above-described methods for carrying out the invention, and variations of the mechanical aspects of the invention that are obvious to those of skill in the mechanical and
20 guide wire and/or catheter arts are intended to be within the scope of the claims.

CLAIMS

We claim:

1. A catheter section comprising :
 - a.) a balloon region from distal of an inflatable member to proximal of an
5 inflatable member,
 - b.) said inflatable member within said balloon region,
 - c.) a flexible joint region within said balloon region, and
 - d.) a wire configured to flex the flexible joint region.
- 10 2. The catheter section of claim 1 wherein the flexible joint is distal of said inflatable member.
3. The catheter section of claim 1 wherein the flexible joint is within said inflatable member.
- 15 4. The catheter section of claim 1 wherein the flexible joint is proximal of said inflatable member.
5. The catheter section of claim 1 wherein the flexible joint region has a
20 flexibility of up to 90°.
6. The catheter section of claim 1 wherein the flexible joint comprises a coil member.
- 25 7. The catheter section of claim 6 wherein the coil member has a section with a pitch which is larger than adjacent coil pitches.

8. The catheter section of claim 1 wherein the flexible joint comprises a braid.

9. The catheter section of claim 8 wherein the braid has a section with a pic which is larger than adjacent pics.

5

10. The catheter section of claim 1 wherein the flexible joint is comprised of a polymer which is softer than adjacent polymers.

11. The catheter section of claim 1 wherein the flexible joint is a region having a wall thickness that is thinner than adjacent wall thickness.

10

12. The catheter section of claim 1 wherein the inflatable member comprises a material selected from the group consisting of elastomers and thermoplastic polymers.

15

13. The catheter section of claim 12 wherein said material is an elastomer.

14. The catheter section of claim 13 wherein said elastomer is selected from the group consisting of silicone rubber, latex rubber, natural rubber, butadiene-based co-polymers, EPDM, polyvinyl chloride, and complex co-polymers such as styrene-ethylene butylene-styrene co-polymers.

20

15. The catheter section of claim 13 wherein said elastomer is silicone rubber.

16. The catheter section of claim 12 wherein the said material is a thermoplastic polymer.

25

17. The catheter section of claim 16 wherein thermoplastic polymer is selected from polyethylene, polypropylene, and Nylon.

18. A catheter for delivering a vaso-occlusive member having a proximal and a distal end, an inflation member, and a manipulatable, flexible joint region and comprising:

a.) an inner tubing member having a lumen and extending between said proximal and distal ends of the catheter;

b.) a guide wire insertable into and removable from said inner tubing lumen and which guide wire is suitable for guiding the catheter when the catheter is advanced through a blood vessel;

c.) said inflation member fluidly connected through an inflation lumen by which the inflatable member is inflated;

d.) a push/pull member having a lumen through which a push/pull wire is inserted for manipulating said flexible joint region,

e.) said push/pull wire for manipulating said flexible joint region, and

f.) said manipulatable, flexible joint region.

19. A catheter section, comprising:

a flexible joint region disposed within said catheter section, said catheter section having a distal end and a proximal end and defining an axis therebetween; and

a wire comprising a distal end and a proximal end and a length therebetween, said wire being configured to move said catheter section distal end about said flexible joint region;

said wire distal end being attached in said catheter section such that a portion of said wire length is angularly disposed in relation to said catheter section axis.

20. The catheter section of claim 19, further comprising:

a balloon region comprising a distal end and a proximal end and defining an axis therebetween; and

an inflatable member disposed in said balloon region.

5 21. The catheter section of claim 19, wherein said portion of wire length is partially wound about said catheter section axis.

 22. The catheter section of claim 20, wherein said portion of wire length is wound about 180° about said catheter section axis.

10

 23. The catheter section of claim 19, wherein said catheter section is configured such that imparting a force to said wire rotates said catheter section about said axis into a helical shape.

15 24. The catheter section of claim 19, wherein said portion of wire length is angularly disposed in a right-handed orientation about said catheter section axis.

 25. The catheter section of claim 19, wherein said portion of wire length is angularly disposed in a left-handed orientation about said catheter section axis.

20

 26. The catheter section of claim 19, wherein said wire moves said catheter section distal end about said flexible joint region up to about 90°.

 27. The catheter section of claim 19, wherein said flexible joint region
25 comprises a coil member.

 28. The catheter section of claim 20 wherein the inflatable member comprises a material selected from the group consisting of elastomers and thermoplastic polymers.

29. The catheter section of claim 28 wherein said elastomer is selected from the group consisting of silicone rubber, latex rubber, natural rubber, butadiene-based co-polymers, EPDM, polyvinyl chloride, and complex co-polymers.

5

30. The catheter section of claim 29, where the elastomer comprises styrene-ethylene butylene-styrene co-polymers.

31. The catheter section of claim 28 wherein thermoplastic polymer is selected
10 from polyethylene, polypropylene, and Nylon.

32. A catheter section, comprising:

a balloon region comprising a distal end and a proximal end and defining an axis therebetween;

15 an inflatable member disposed in said balloon region;

a flexible joint region disposed within said balloon region;

a tubing member further disposed in said balloon region, said tubing member having a distal end and a proximal end and an axis therebetween, said tubing member having a variable wall thickness; and

20 a wire configured to move said distal end about said flexible joint region, said wire being disposed within said tubing member.

33. The catheter section of claim 32, wherein said tubing member comprises a first wall thickness at a location proximal of said distal end and a second wall thickness at
25 said distal end, said first wall thickness being greater than said second wall thickness.

34. The catheter section of claim 32, wherein said tubing member further comprises a plurality of consecutive tube sections, said tube sections each having a wall thickness less than an adjacent proximal tube section.

5 35. The catheter section of claim 32, where said tubing member has a tapered wall.

36. A catheter section, comprising:
a flexible joint region disposed within said catheter section, said catheter section
10 having a distal end and a proximal end and defining an axis therebetween; and
a wire comprising a distal end and a proximal end and a length therebetween, said wire being configured to move said catheter section distal end about said flexible joint region, said wire distal end being attached in said catheter section such that a portion of said wire length is angularly disposed in relation to said catheter section axis;
15 said catheter section defining an entry through which a guidewire is inserted.

37. The catheter section of claim 36, further comprising:
a balloon region comprising a distal end and a proximal end and defining an axis therebetween; and
20 an inflatable member disposed in said balloon region.

38. The catheter section of claim 36, wherein said entry is proximal of said flexible joint region.

25 39. The catheter section of claim 36, wherein said portion of wire length is partially wound about said catheter section axis.

40. The catheter section of claim 39, wherein said portion of wire length is wound about 180° about said catheter section axis.

41. A catheter section, comprising:

5 a flexible joint region disposed within said catheter section, said catheter section having a distal end and a proximal end and defining an axis therebetween; and

a wire comprising a distal end and a proximal end and a length therebetween, said wire being configured to move said catheter section distal end about said flexible joint region;

10 said wire being further configured to move said catheter section distal end about said catheter section axis.

42. The catheter section of claim 41, further comprising:

15 a balloon region comprising a distal end and a proximal end and defining an axis therebetween; and

an inflatable member disposed in said balloon region.

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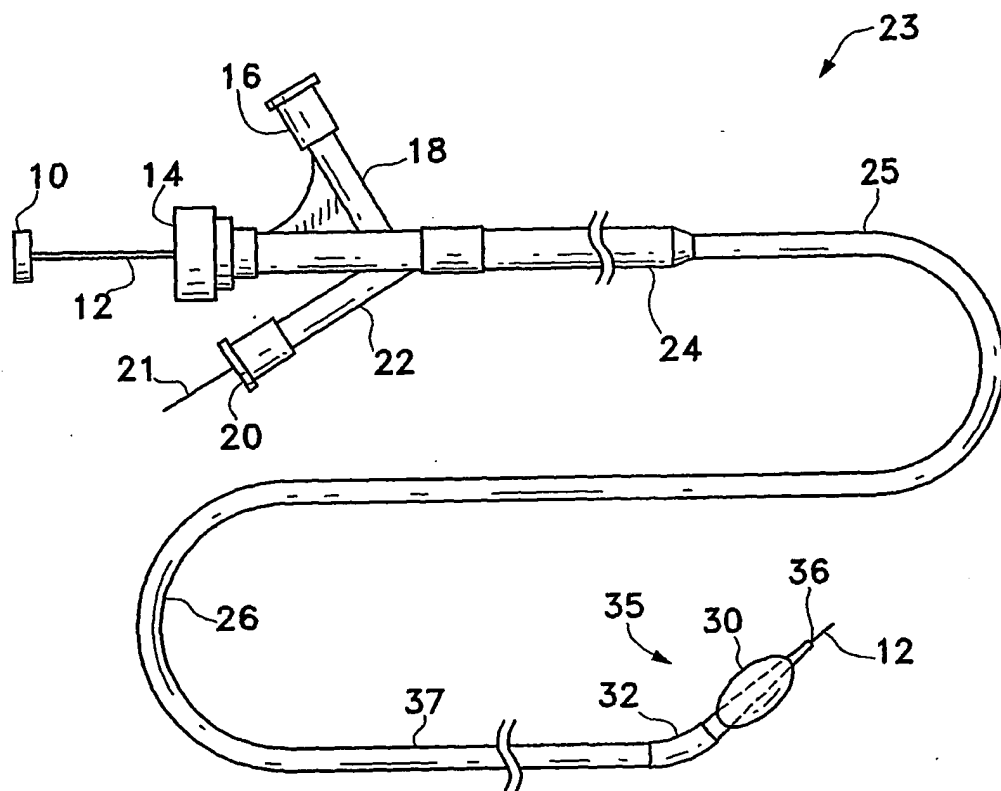


Fig. 1A

Fig. 1B

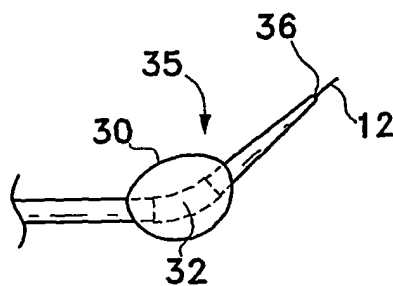
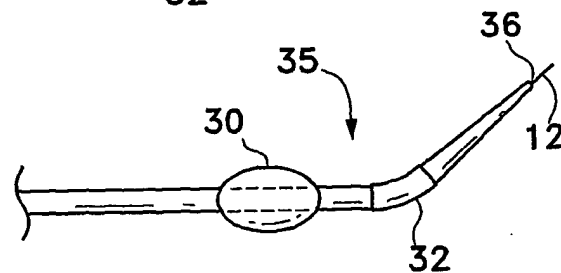


Fig. 1C



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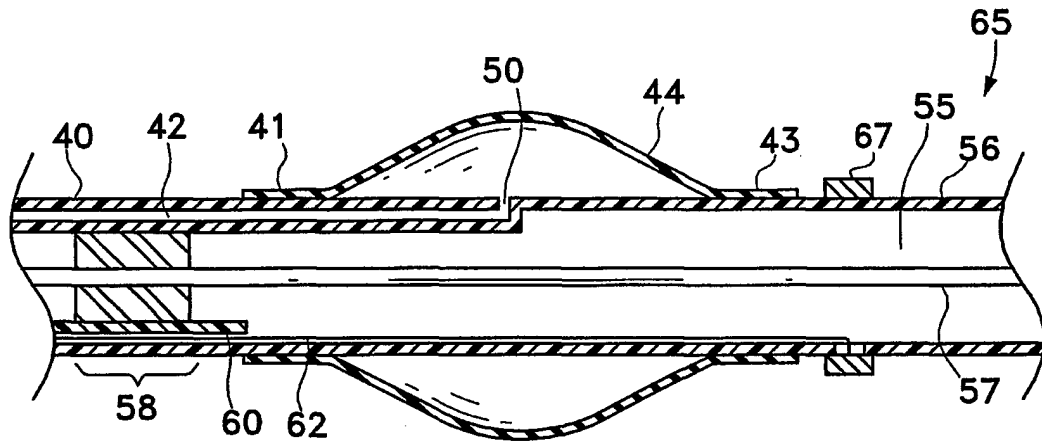


Fig. 2A

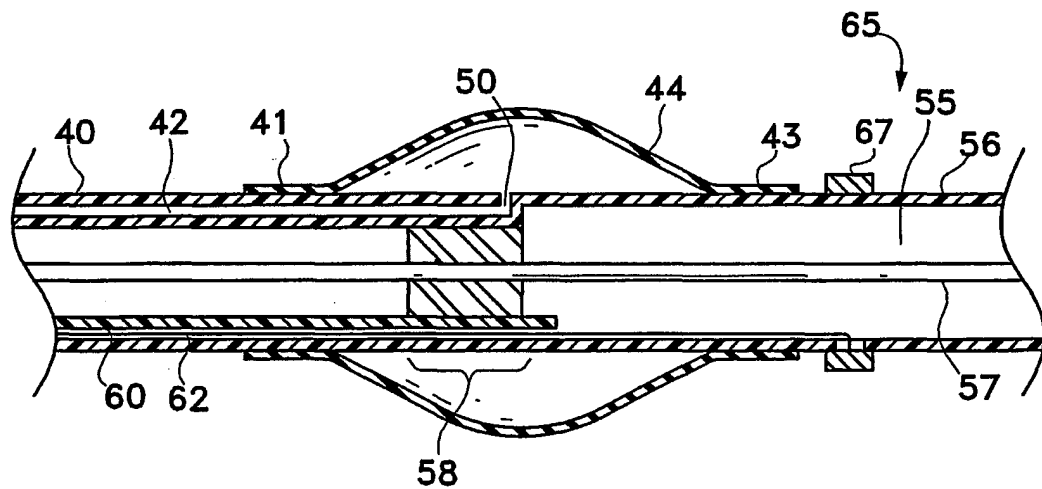


Fig. 2B

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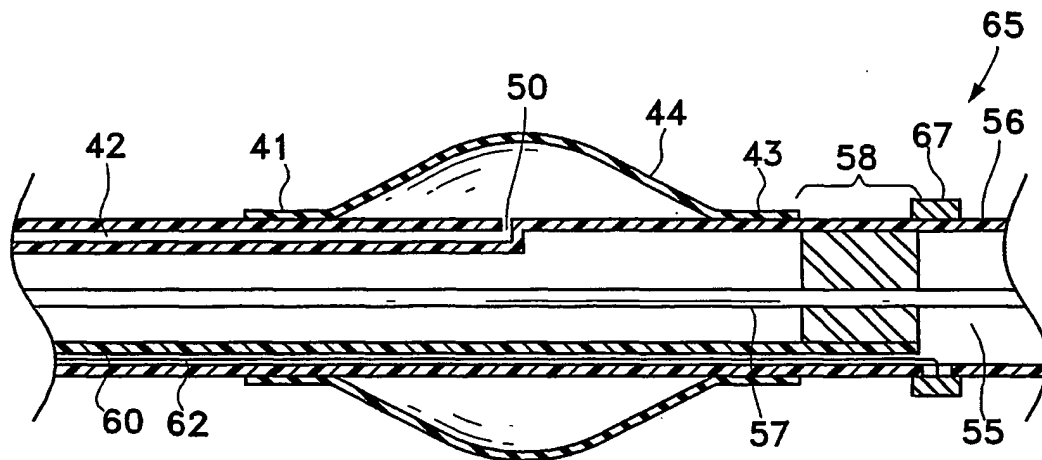


Fig. 2C

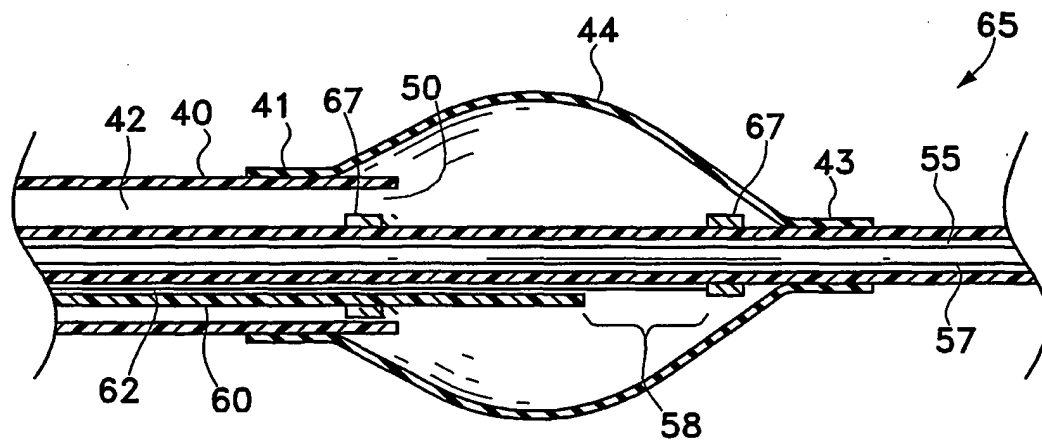


Fig. 2D

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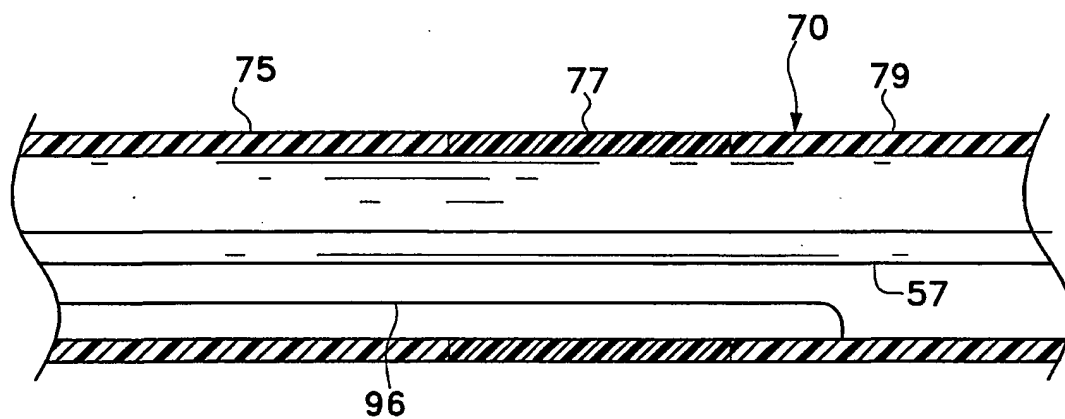


Fig. 3A

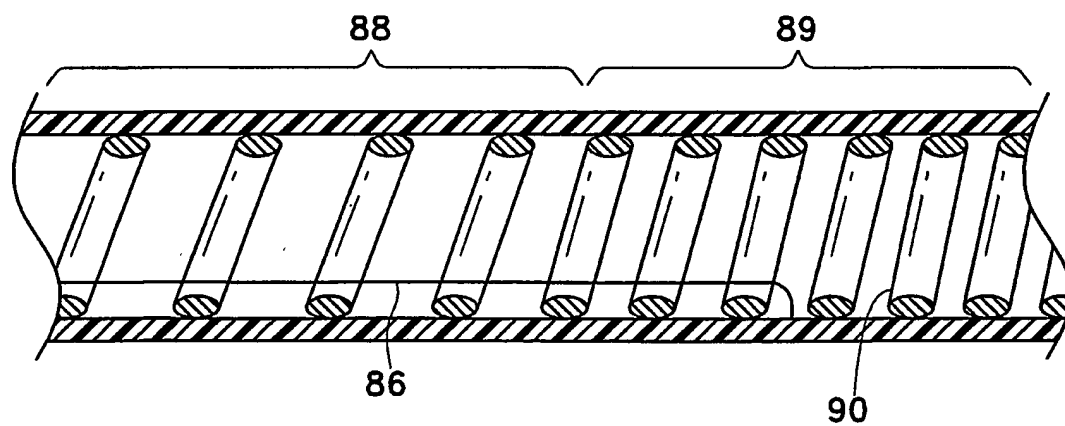


Fig. 3B

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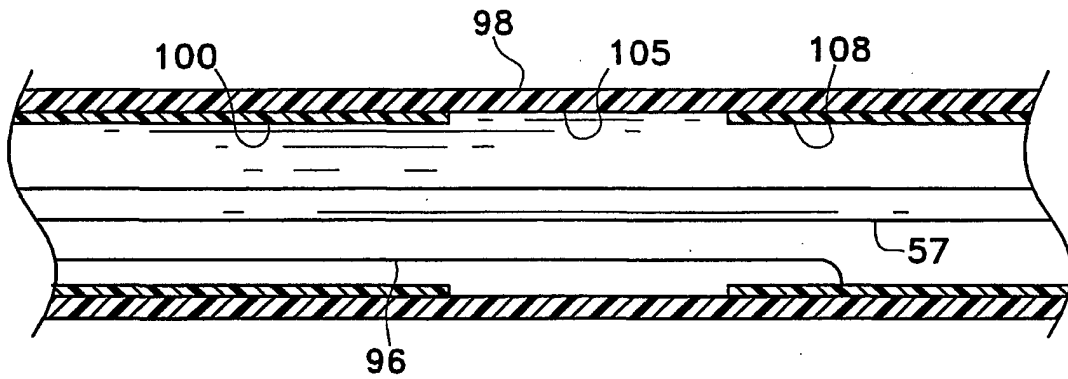


Fig. 3C

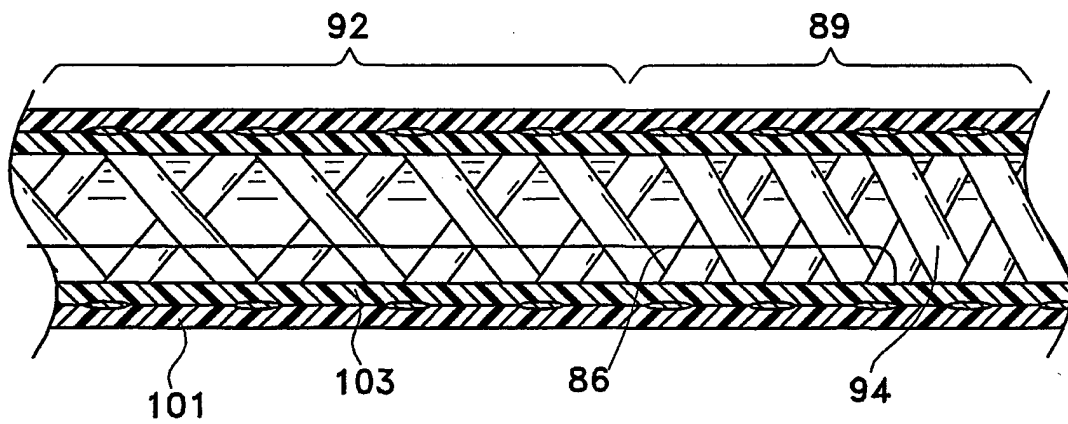


Fig. 3D

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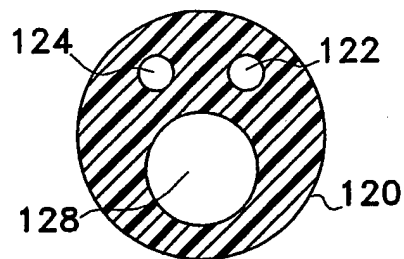


Fig. 4A

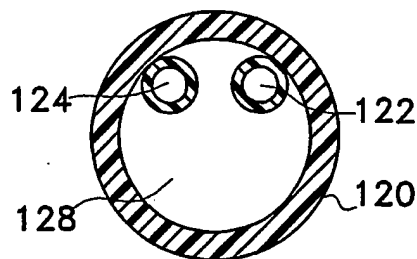


Fig. 4B

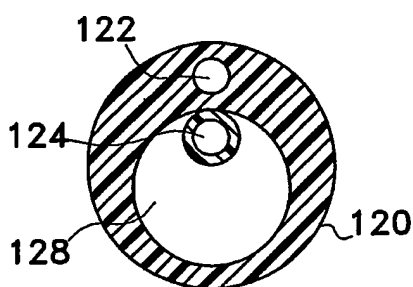


Fig. 4C

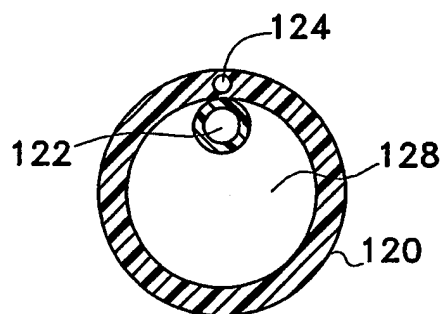


Fig. 4D

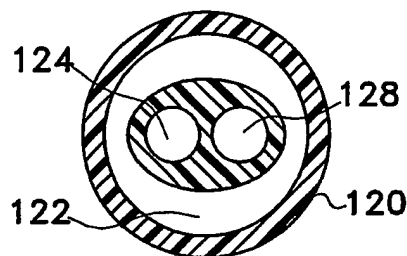


Fig. 4E

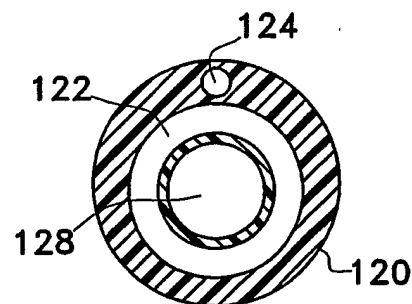


Fig. 4F

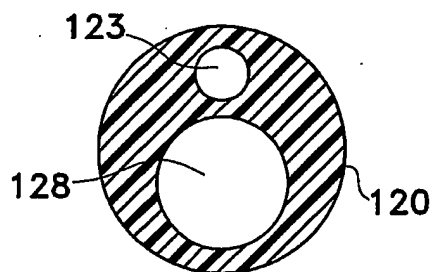


Fig. 4G

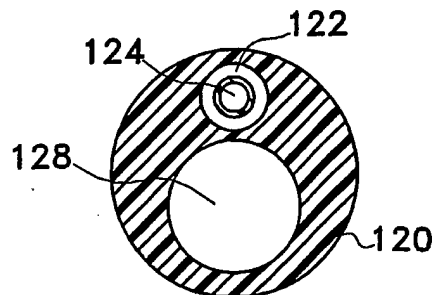


Fig. 4H

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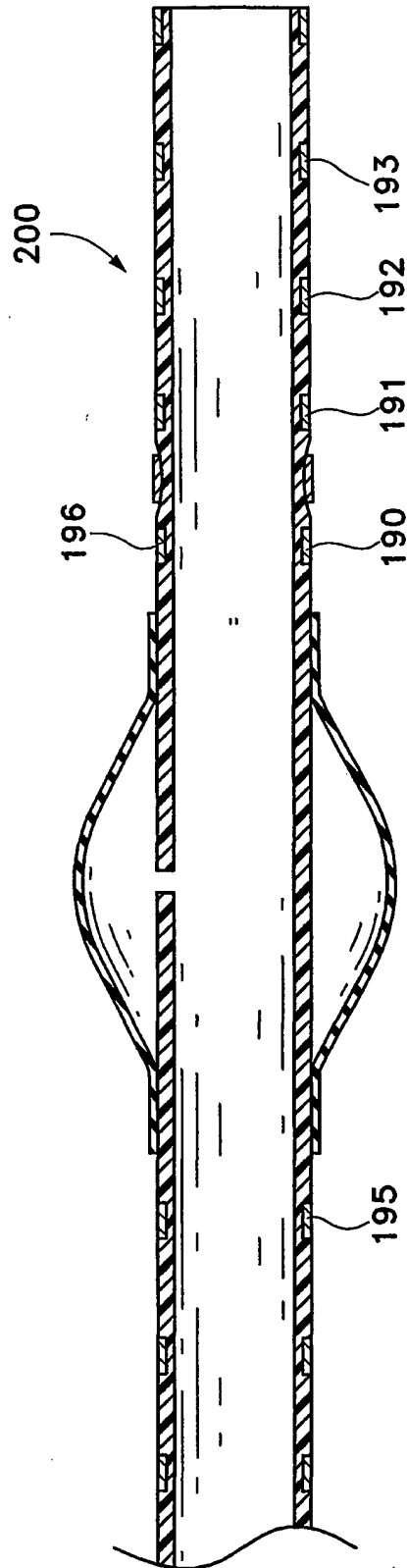


Fig. 5

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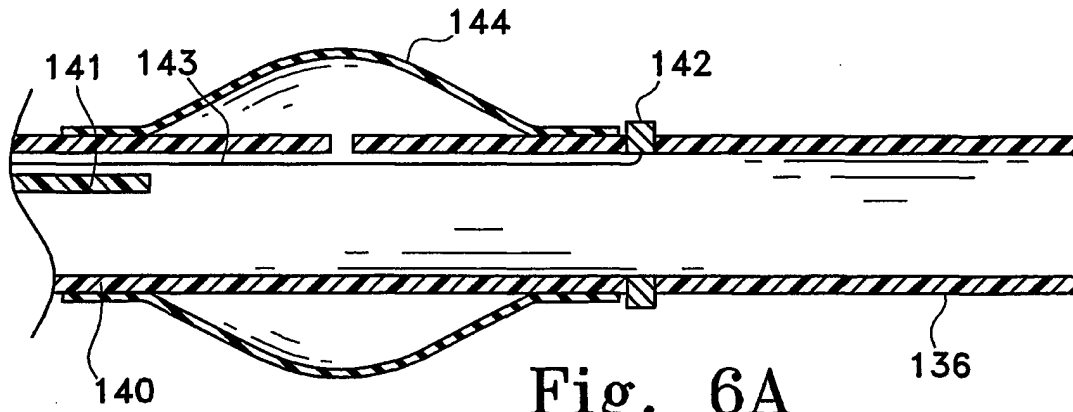


Fig. 6A

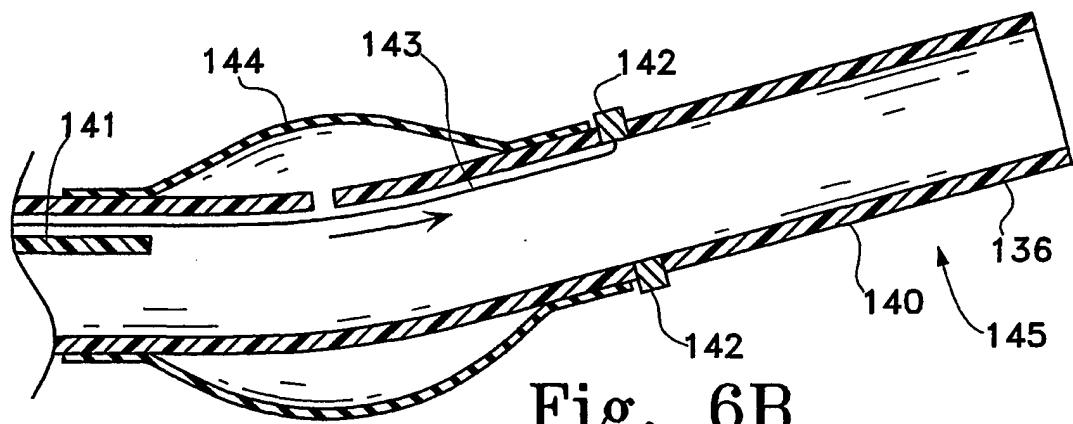


Fig. 6B

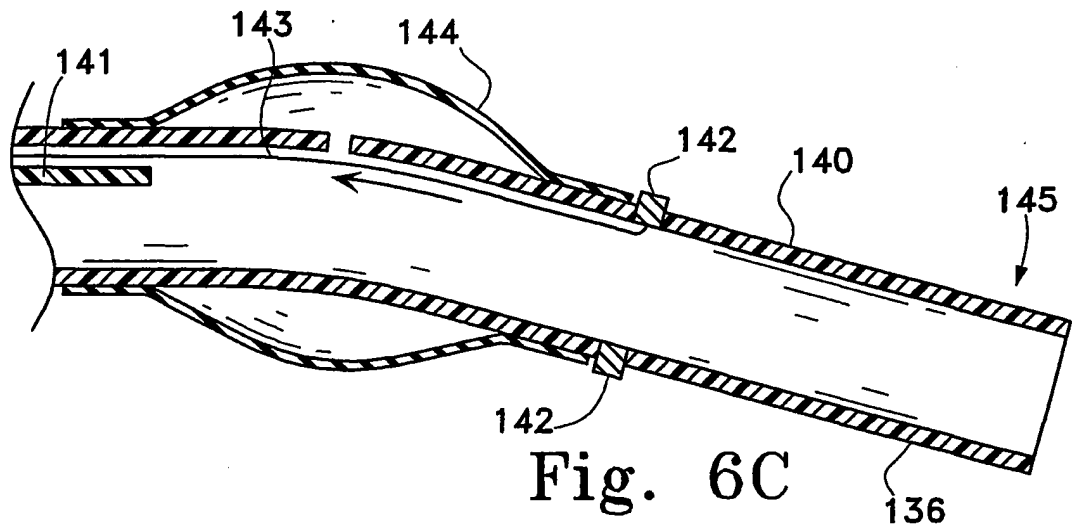


Fig. 6C

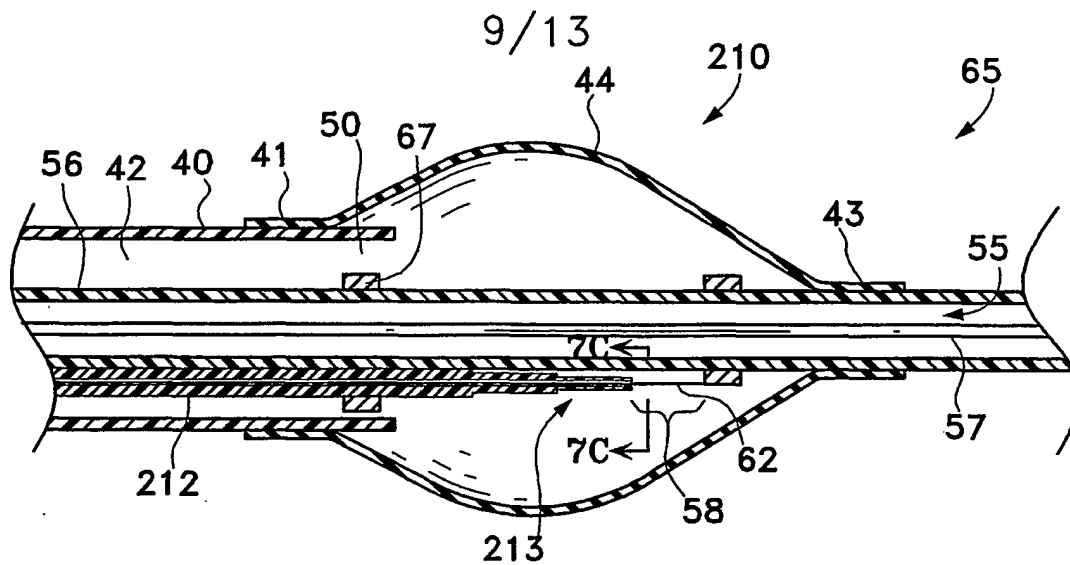


Fig. 7A

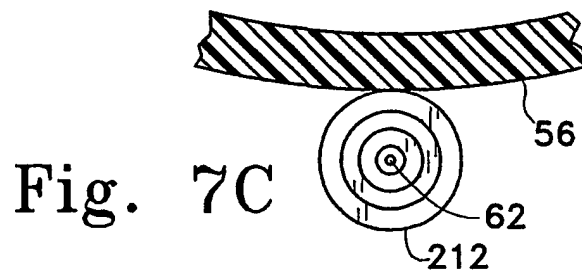


Fig. 7C

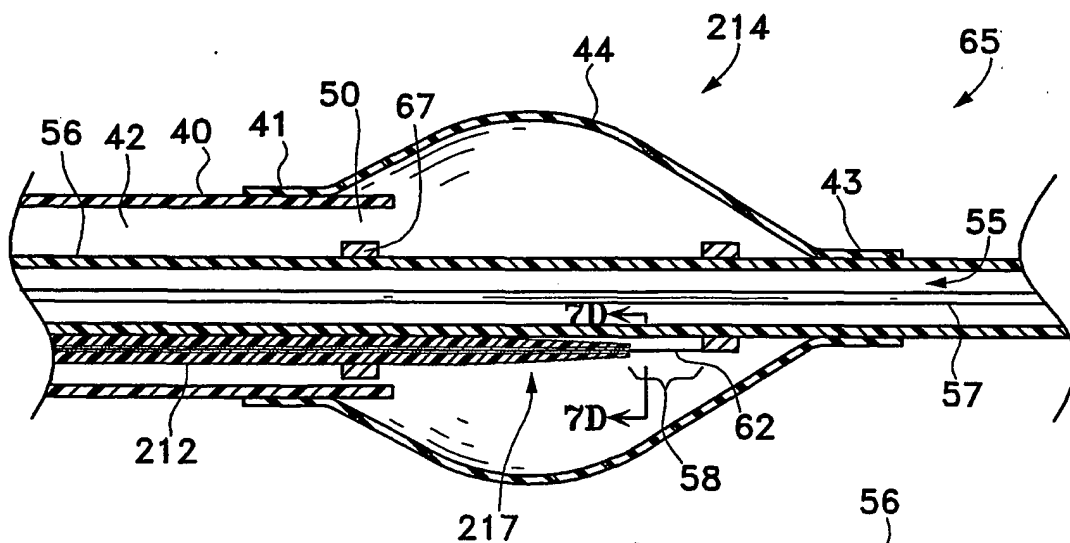


Fig. 7B

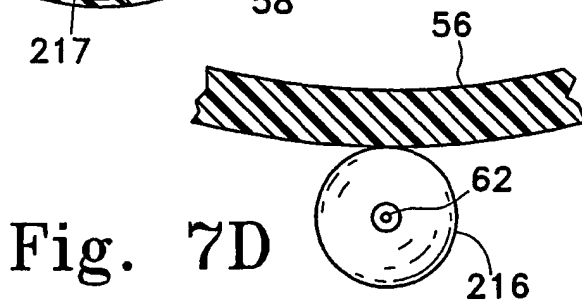


Fig. 7D

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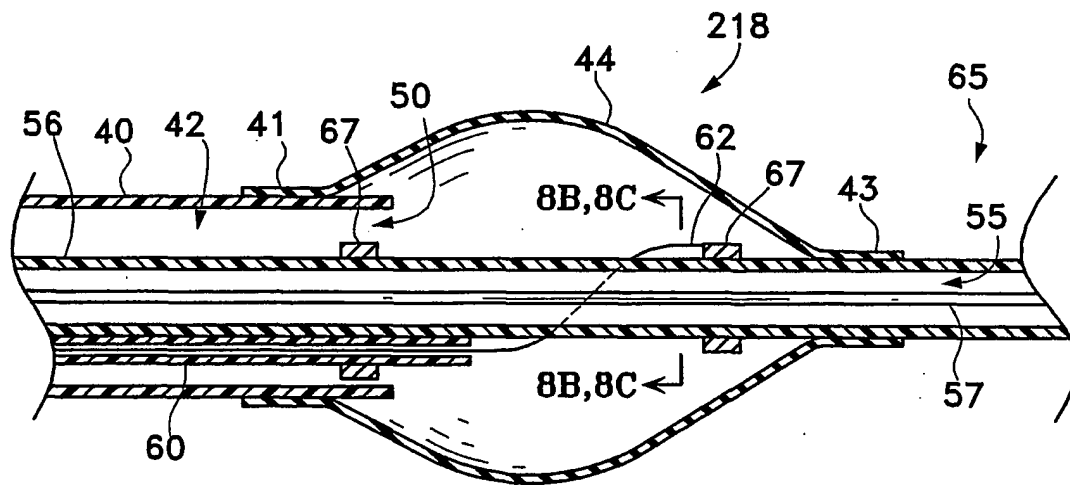


Fig. 8A

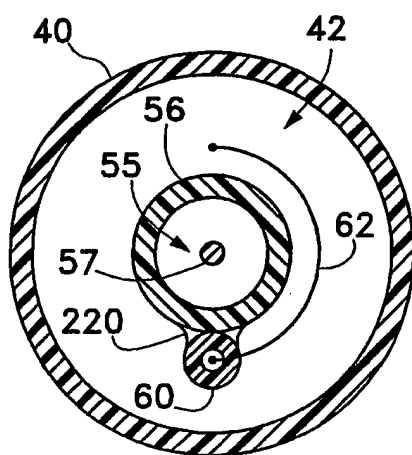


Fig. 8B

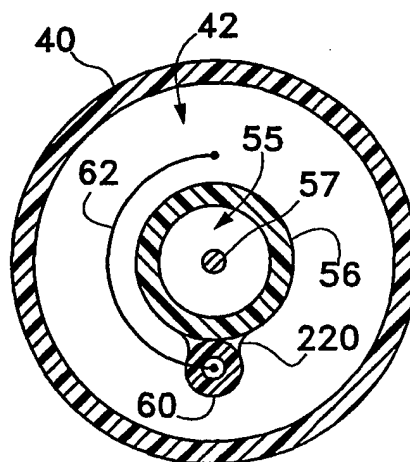


Fig. 8C

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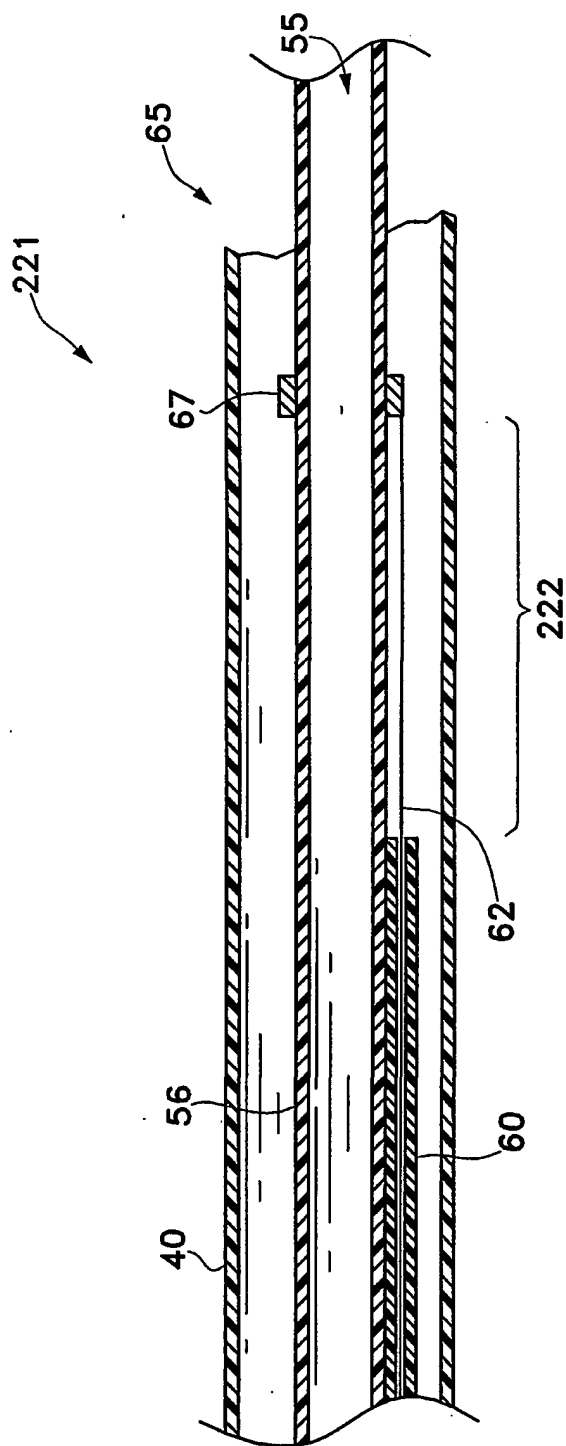


Fig. 9

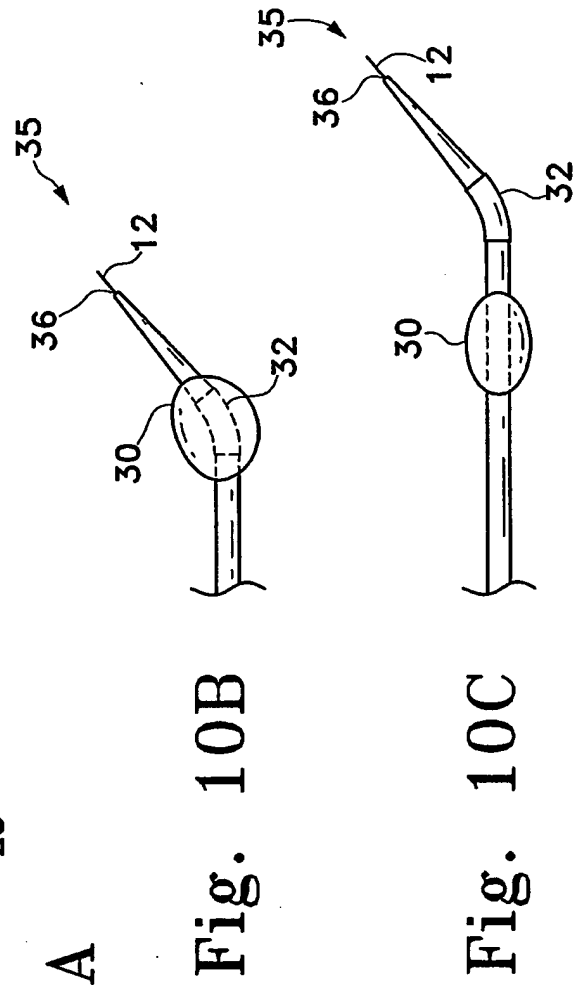
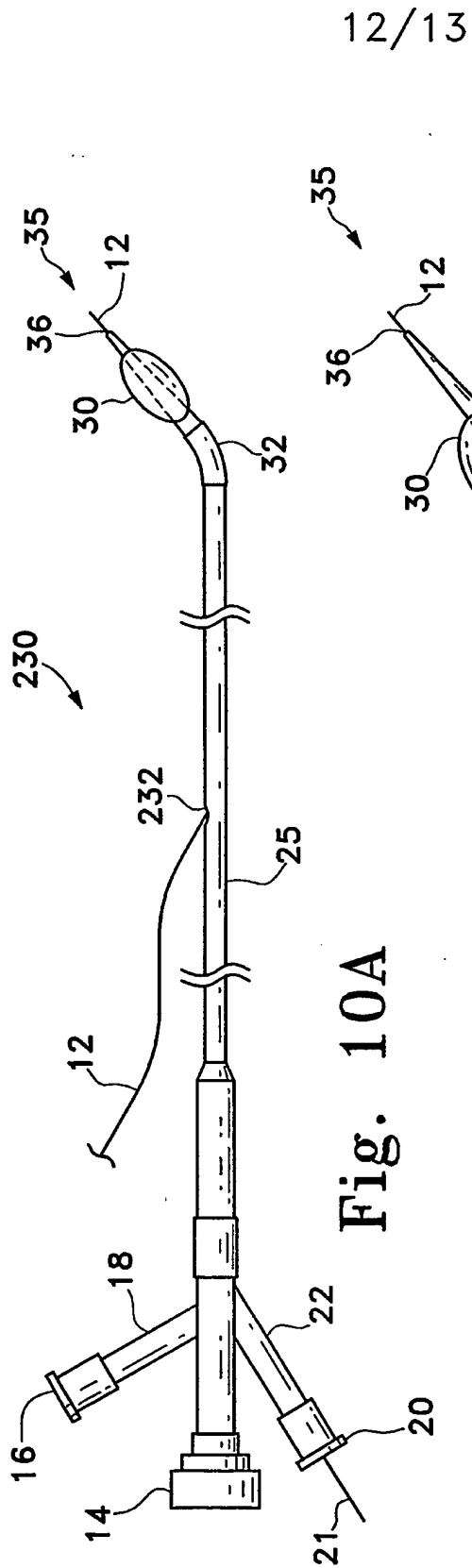


Fig. 11A

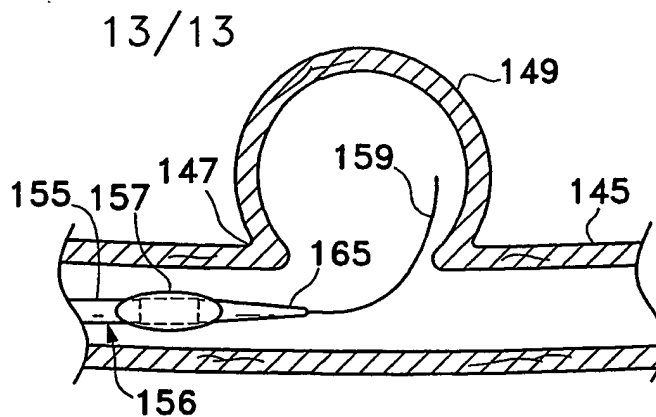


Fig. 11B

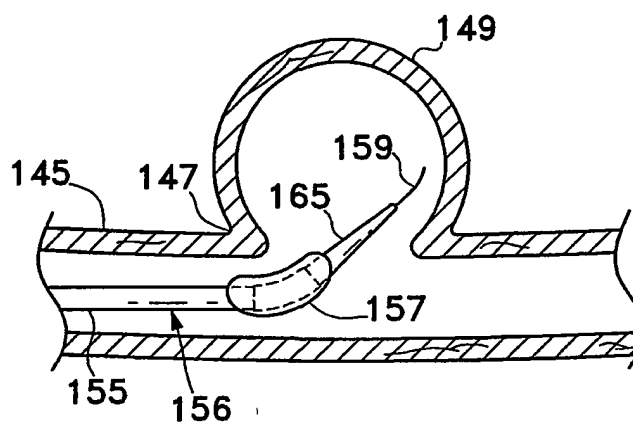


Fig. 11C

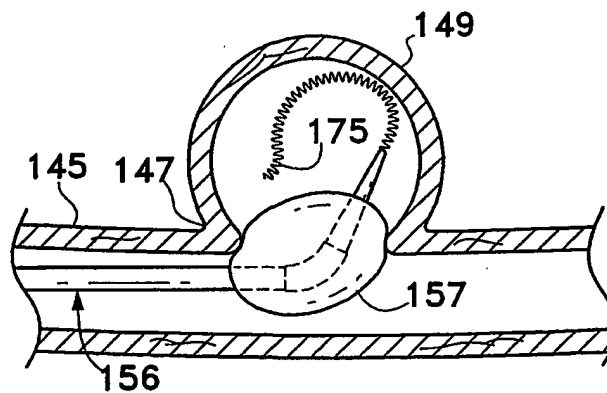


Fig. 11D

